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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,070	12/09/2003	Christian Rosenquist	60686-CIP(46865)	2948

7590 06/29/2005
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EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,070

Applicant(s)

ROSENQUIST ET AL

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5 and 6 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12-9-2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>6-23-2005</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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1. Claims 1-6 are pending in this application.

2. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: (i) measuring or removing collagen degradation products present in the sample; (ii) reacting antibodies with a sample comprising collagen; (iii) incubating the sample containing the antibodies to form reaction products or complexes; and (iv) detecting the reaction products or antibody-collagen complexes.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: (i) a step that correlates the number of complexes formed to the rate of type II collagen resorption.

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Eyre or in the alternative under 35 U.S.C. 103(a) as being unpatentable over Eyre (US 5,320,970).

Eyre discloses a method for determining collagen degradation by quantitating the concentration of a peptide capable of binding to monoclonal antibodies. Note the abstract. Eyre discloses preparation of monoclonal antibody to "[A fraction enriched in the peptide of Formula III (indicative of bone collagen degradation)...]" Eyre also disclose screening for reactive monoclonal antibodies using P1 antigen. See column 9, lines 34-68. In addition, Eyre disclose "[Sandwich assays were also shown to work using the P1-specific monoclonal antibody and a polyclonal anti-serum raised in rabbits

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against conjugated P1. Either P1-specific monoclonal antibodies, polyclonal antiserum, binding specifically to P1 from urine, in a detectable manner using standard ELISA and other immunoassay protocols.]” See column 10, lines 33-44.

With respect to the limitations of instant claim 2 which recites “[A method of measurement of the rate of type II collagen resorption]”, Eyre disclose a method for determining the rate of bone resorption which reacts a body fluid with “[A composition comprising peptides produced by digesting bone collagen with a protease capable of generating peptides that bind to the monoclonal antibody 1H11...]”. See column 15, lines 14-23 and column 16, lines 1-32. In regards to the type II collagen fragments, Eyre disclose “[The P2 telopeptide has a hydroxylysyl pyridinoline cross-link derived from the C-terminal telopeptide domain of type II collagen and the following amino acid sequence:...]” With respect to the instant epitope claim limitations, Eyre disclose “[Characteristics of a Preferred Epitope The epitope recognized by the antibody Mab-1H11 is embodied in the structure of P1.]” See column 10, line 44-68 and column 11, lines 1-55. Hence, Eyre disclose all the limitations described in the instant claims except for addressing a step for measuring the amount of type II collagen antibody-fragment complexes formed in the collagen sample.

However, regarding the step of measuring the amount of type II collagen antibody-fragment complexes formed in the instant invention, Eyre disclose (i) a method for determining the rate of bone resorption by a biological sample with specific antibodies; and (ii) Eyre disclose the P2 peptide has been derived from the peptide domain of type II collagen and an amino acid sequence. Note column 9, lines 60-68;

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and column 10, line 44-68 and column 11, lines 1-55. Also, it is noted that type II collagen antibody-fragment complexes would inherently form in the collagen samples of the Eyre disclosure because bone collagen naturally comprises type II collagen.

Hence, the Eyre reference discloses all the claimed limitations except for addressing the inherent formation of type II collagen complexes in bone collagen which anticipates or renders obvious the present invention.

The burden of proof is on applicants to show patentably distinct differences between the instant methods and the sandwich assays described in the Eyre disclosure.

4. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


5. The Rosenquist et al document (US 6,660,481) has been cited to further show the state of this art.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is 571-272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LOUISE N. LEARY
PRIMARY EXAMINER

June 23, 2005